

Dated: March 26, 2007.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. E7-6008 Filed 3-30-07; 8:45 am]

BILLING CODE 4163-18-P

Dated: March 26, 2007.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

[FR Doc. E7-6022 Filed 3-30-07; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, National Center for Health Statistics

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS) announces the following meeting of the aforementioned committee.

*Times and Dates:* 2 p.m.-5:30 p.m., April 26, 2007. 8:30 a.m.-2 p.m., April 27, 2007.

*Place:* NCHS Headquarters, 3311 Toledo Road, Hyattsville, Maryland 20782.

*Status:* Open to the public, and limited only to the space available. The meeting room accommodates approximately 100 people.

*Purpose:* This committee is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

*Matters to be Discussed:* The agenda will include welcome remarks by the Director, NCHS; introduction of members and key NCHS staff; scientific presentations and discussions; continued discussion of the review of the natality program; discussion of upcoming program reviews and an open session for comments from the public.

Requests to make oral presentations should be submitted in writing to the contact person listed below. All requests must contain the name, address, telephone number, and organizational affiliation of the presenter.

Written comments should not exceed five single-spaced typed pages in length and must be received by April 13, 2007.

The agenda items are subject to change as priorities dictate.

#### Contact Person For More Information:

Virginia S. Cain, Ph.D., Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7211, Hyattsville, Maryland 20782, telephone (301) 458-4500, fax (301) 458-4020.

The Director, Management Analysis and Services Office, has been delegated the authority to sign *Federal Register* notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005E-0245]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; KEPIVANCE

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for KEPIVANCE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase

begins when the exemption to permit the clinical investigations of the human biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial complete submission of an application to market the human biological product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product KEPIVANCE (palifermin). KEPIVANCE is indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic stem cell support. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for KEPIVANCE (U.S. Patent No. 5,677,278) from Chiron Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 14, 2006, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of KEPIVANCE represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for KEPIVANCE is 3,303 days. Of this time, 3,119 days occurred during the testing phase of the regulatory review period, while 184 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* December 2, 1995. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 2, 1995.

2. *The date the application was initially submitted with respect to the human biological product under section*

*505(b) of the act:* June 15, 2004. The applicant claims May 14, 2004, as the date the biologics license application (BLA) for KEPIVANCE (BLA 125103) was initially submitted. However, FDA records indicate that the final reviewable unit of BLA 125103 was submitted on June 15, 2004.

*3. The date the application was approved:* December 15, 2004. FDA has verified the applicant's claim that BLA 125103 was approved on December 15, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,417 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 1, 2007. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 1, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 2007.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E7-6053 Filed 3-30-07; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration [Docket No. 2003E-0256]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; RANEXA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for RANEXA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period

may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product RANEXA (ranolazine). RANEXA is indicated for treatment of chronic angina. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for RANEXA (U.S. Patent No. 4,567,264) from Roche Palo Alto, L.L.C., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 5, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of RANEXA represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for RANEXA is 6,770 days. Of this time, 5,645 days occurred during the testing phase of the regulatory review period, while 1,125 days occurred during the approval phase. These periods of time were derived from the following dates:

*1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* July 18, 1987. The applicant claims July 10, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 18, 1987, which was 30 days after FDA receipt of the IND.

*2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* December 30, 2002. FDA has verified the applicant's claim that the new drug application (NDA) for RANEXA (NDA 21-526) was initially submitted on December 30, 2002.

*3. The date the application was approved:* January 27, 2006. FDA has verified the applicant's claim that NDA 21-526 was approved on January 27, 2006.

This determination of the regulatory review period establishes the maximum potential length of a patent extension.